

Appl. No. : 10/722,367
Filed : November 25, 2003

AMENDMENTS TO THE SPECIFICATION

Amendments to the specification are as follows. Only those paragraphs being amended herein show their changes in highlighted form, where insertions appear as underlined text (e.g., insertions), while deletions appear as strikethrough text (e.g., ~~deletions~~) or enclosed in double brackets (e.g., [[deletion]]).

[0011] Accordingly, one embodiment a bifurcation graft deployment system, comprises an elongate, flexible catheter body, having a proximal end and a distal end and comprising an outer sheath and an inner core that is axially moveable with respect to the outer sheath. A main vessel graft restraint comprising a first peelable cover ~~for~~ restrains a main vessel portion of a bifurcated graft. A first branch vessel graft restraint restrains a first branch vessel portion of the graft. A second branch vessel graft restraint restrains a second branch vessel portion of the graft. The first peelable cover is coupled to a main branch release element and wherein each of the main vessel graft restraint, first branch vessel graft restraint, and the second branch vessel graft restraint are positioned within the catheter body in a graft loaded condition.

[0095] Preferably, the proximal end 404 of the peelable sheath 100 is provided with a leader 412 of sheath material to ~~facilitate~~facilitating positioning the joint 410, as will be explained below. The peelable sheath 400 is preferably also provided with a peel start point 414 such as a slit, perforation, V-shaped cut, or otherwise as will be apparent to those of skill in the art in view of the disclosure herein. The peelable sheath 400 preferably further includes a perforation line 416, crease, recess or other tear facilitating modification extending axially there along to facilitate predictable tearing of the material. In the illustrated embodiment, the perforation line 416 comprises a series of slits that are about 2.0 millimeters long and separated by a distance of about 1.5 millimeters.

[0087] Preferably, the first cylindrical portion 362 has an outside diameter that is approximately equal to the outside diameter of the outer sheath 328. The tapered portion 360, in turn, preferably tapers from an outside diameter that is approximately equal to the outside

Appl. No. : 10/722,367
Filed : November 25, 2003

diameter of the first cylindrical portion 362 to an outside diameter that is at least about 50% smaller at the distal end thereof.

[0091] In the embodiment illustrated in Figure 12, a distal end 382 of the hypotube 376 is frictionally fitted within the proximal end 378 of the distal tip 358. To aid the frictional fit, the distal end 382 may be provided with a one or more ridges or grooves 383. In a similar manner, a proximal end 384 of the distal hypotube 376 is frictionally fitted within the distal end 380 of the central core 330. The proximal end 384 of the distal hypotube 376 may also be provided with one or more ridges or grooves 383. In other embodiments, the distal hypotube 376 can be connected to distal tip 358 and/or the central core 330 by thermal bonding, adhesive bonding, and/or any of a variety of other securing techniques known in the art which can also be used in addition to the frictional fit described above.

[0098] The second tubular sheath 412 is secured to the contralateral guidewire 374, which extends outside the catheter 320 at a point 416 (see Figure 9B), such as may be conveniently provided at the junction 386 between the outer tubular sheath 328 and the distal tip 358. In the illustrated embodiment, the contralateral guidewire 374 extends through the groove 372 provided in the distal tip 358 and described above. The second tubular sheath 412 is adapted to restrain the contralateral branch 396 of the graft 390 in the reduced profile. In one embodiment of the invention, the second tubular sheath 412 has an outside diameter of about .215" and an axial length of about 7.5 cm. In the loaded configuration (Figure 9B), the second tubular sheath 412 can have a significantly smaller cross-section than the first tubular sheath 411, due to the presence of the hypotube 376 within the ipsilateral branch 394.

[0102] Referring to FIG. 17, the outer sheath 328 can be distally advanced and contralateral guidewire 374 withdraw so as to position the iliac position the branches 394, 396 of the graft 390 within the iliac arteries as illustrated. In this embodiment, the outer sheath 328 also provides support for the ipsilateral branch 394. Referring to FIG. 18, proximal traction is applied to the aortic trunk release wire 355. In the illustrated embodiment, the distal end 388 of the outer sheath 328 provides a fulcrum for minimizing injury to the adjacent tissue as proximal

Appl. No. : 10/722,367
Filed : November 25, 2003

traction is applied to the aortic trunk release wire 355~~4355~~. Proximal retraction of the release wire 355 pulls the peelable sheath 400 down into the outer sheath 328. As shown in FIG. 19, retraction of the release wire 355 pulls the peelable sheath 400 proximally along the aortic trunk 392 such that the aortic trunk 392 is released from the distal end first. Further proximal retraction of the release wire 410 causes the peelable sheath 400 to tear or split distally thereby permitting complete retraction of the peelable sheath 400 from the aortic trunk 392 as illustrated in FIG. 20.

[0106] In this embodiment, the ipsilateral branch 394 is compressed within a second peelable sheath 420, which preferably is configured in a manner similar to the peelable sheath 410 described above. The second peelable sheath 420 is secured to an ipsilateral branch release wire 422, which as with the aortic trunk release wire 410 can extend proximally through the catheter 320 between the outer sheath 328 and the inner core 330. The ipsilateral branch release wire 422 can exit the catheter 320 through the release wire port 344 (see FIG. 9A). ~~[[Or]]~~Of course, in a modified embodiment, a second release port can be provided.

[0110] The graft 430 is compressed within a peelable sheath 442, which preferably is configured in a manner similar to the peelable sheath 410 described above. The peelable sheath 442 is secured to a release wire 444 through a joint 446. The release wire 444 preferably extends through the catheter 432 between the outer sheath 328 and the inner core 330~~328~~.

[0113] After the catheter 432 is in position, the outer sheath 328 is proximally withdrawn while maintaining the general axial position of the catheter 432, thereby exposing the graft 430. A device proximal (anatomically inferior) portion 462 of the graft 130 is then released by proximally withdrawing ~~proximal~~ the proximal release wire 458. After the proximal portion 462 of the graft 430 is released, the distal portion 464 of the graft is released by proximally withdrawing the distal release wire 454. Preferably, the distal portion 464 is released after the proximal portion 462 so as to prevent a "sail" effect in the thoracic area due to the high pressure, although release can be accomplished in the reverse order.